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| 09/730,010 | 12/04/2000 | Thomas R. Jenkins | 15916-277 | 6595 |

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| EXAMINER | |
|---|---|
| NGUYEN, CAMTU TRAN | |
| ART UNIT | PAPER NUMBER |
| 3772 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/730,010 | JENKINS ET AL. | |
| | Examiner | Art Unit | |
| | Camtu T. Nguyen | 3772 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *29 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *14-17,21-30,38,39,45 and 46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-17,21-30,38,39,45 and 46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Response to After Final Amendment*

This Office Action is responding to applicant's After Final Amendment filed on 4-29-2008.

Applicant's request for withdrawal of the previous finality has been carefully considered and deemed persuasive. The Finality of 4-17-2008 has been withdrawn and the issuance of a corrected Office Action presented below.

### *Response to Amendment*

This Office Action is responding to applicant's amendment filed on 1-16-2008. Claims 17 & 21 have been amended. Claims 1-13, 18-20, 31-37, and 40-44 have been cancelled. Claims 45 & 46 are newly added.

Applicant's comments directed to the 103(a) rejection of claims 14-16 and 38 are noted, however, are not persuasive. Particularly, applicant stated that the Office Action was not clear with regards to the coagulation body is supported on the elongated body distal region. The Swanson et al reference discloses that the spline element (172) can be attached to the elongated body (184) distally (column 17 lines 22-23), thus, making the spline (172) the distal region of the elongated body (184), thereby, it is clearly that the coagulation body is supported on spline element (172), which is indeed the distal region of the elongated body (184). With regards to applicant's comments directed to the previous Office Action ignoring the "inflatable" aspect of the coagulation body, The Swanson et al discloses the size & spacing of the electrodes (28) on

various structures can vary. Alternatively, the electrodes (28) can be space & sized for creating continously, long lesion pattern (418) as shown in Figure 64 and such pattern (418) can be achieved using elongated electrode element from a porous material as shown in Figure 82. As mentioned in the previous Office Action, embodiment of Figures 82-84 illustrates the inflatable aspect of the coagulation/electrode body. Clearly, it would have been obvious to one skilled the art to use the probe of Figure 25 utilizing the alternative inflatable electrode of Figures 82-84 in a procedure that would require additive heating effects during tissue contact. Applicant's comments directed to claim 16, the Swanson et al reference discloses the electrode (28) can serve many different purposes, being a sensing element is one of them (column 7 lines 45-48). For purposes of demonstrating for claim 16, Figure 25 illustrates 5 different electrodes (28), it is not out of the ordinary to assign one of the five electrodes (28) to be a sensing element while assign the rest of the other four electrodes (28) to the alternative electrodes of Figures 82-84 for ablating/coagulating purposes. With regards to the limitations recited in the wherein statement in claim 16, particularly required the "sensing element" electrode on one side of the hinge portion and the "coagulation electrode" on the other side, it would have been clearly and obvious to one having ordinary skill in the art at the time the invention was made to have the "sensing electrode" on a different side of the hinge portion from the "coagulation electrode", since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

The 103(a) rejection applied to claims 14-15 and 38 in the previous Office Action stands. The claims, as amended, have been carefully considered but deemed not allowable in view of the following rejection(s).

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14 & 17 recites the limitation "the distal end" in line 7 and in line 6, respectively. There is insufficient antecedent basis for these limitations in the claims.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 14-15 and 38 are rejected under 35 U.S.C. 102(a) as being anticipated by Swanson et al (U.S. Patent No. 6,076,012). Swanson et al discloses in Figure 82 a distal end (426) of the electrode body (428) is coupled to a flexible joint (440), which is part of the sheath (442), advancement of electrode body (428) from sheath (442) creates loop (424), the electrode body (428) enveloped by porous material (430) and heated by spaced-apart electrodes (429). With regards to the hinge, the Swanson et al discloses in Figures 33-36 the loop structure (232) comprises a flexible spline (234) which possesses a flattened cross sectional geometry (column 19 lines 27-34), the spline (234) acts as a hinge.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson et al (U.S. Patent No. 6,076,012). Swanson et al discloses the embodiment of Figure 25 comprising elements as recited in these claims including the sensing element, the Swanson et al discloses in Figure 3A at least two temperature sensing elements (540). With regards to the limitations recited in the wherein statement in claim 16, particularly required the "sensing element" electrode on one side of the hinge portion and the "coagulation electrode" on the other side, it would have been clearly and obvious to one having ordinary skill in the art at the time the invention was made to have the "sensing electrode" on a different side of the hinge portion from the "coagulation electrode", since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

Claims 14-16 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson et al (U.S. Patent No. 6,076,012) and further in view of Crowley (U.S. Patent No. 5,715,825). Swanson et al reference discloses the embodiment of Figure 25 comprising an elongated body (184) comprising a catheter carried within the outer member (12), the distal region of the elongated body (184) includes a flexible spline (172) that includes a hinge portion (186). This embodiment further comprising a coagulation portion (182) but with regards to the coagulation body being inflatable, Swanson et al discloses alternatively, the electrodes (28) can

be space & sized for creating continously, long lesion pattern (418) as shown in Figure 64 and such pattern (418) can be achieved using elongated electrode element from a porous material as shown in Figure 82. The Examiner maintains that it would have been obvious to provide the inflatable structure from the embodiment of Figures 82-84 on the embodiment of Figure 25 to provide an alternative treatment device, such as during a procedure that would require additive heating effects during tissue contact.

Regarding claims 15 & 16, the embodiment of figure 25 includes the coagulation body proximal to the hinge element and the electrodes (28) can be used to sense in heart tissue (column 7 lines 45-48). With regards to the limitations recited in the wherein statement in claim 16, particularly required the "sensing element" electrode on one side of the hinge portion and the "coagulation electrode" on the other side, it would have been clearly and obvious to one having ordinary skill in the art at the time the invention was made to have the "sensing electrode" on a different side of the hinge portion from the "coagulation electrode", since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

Claims 17 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson et al (U.S. Patent No. 6,076,012) and further in view of Crowley (U.S. Patent No. 5,715,825). Swanson et al discloses in Figure 82 a probe comprising an elongated body (424) comprising a catheter carried within the outer member or sheath (442) interior bore, the distal end (426) of elongated body (424) operably connected to the distal end (440) of outer member or sheath (442). Figure 84 illustrates the tissue coagulation structure (430) supported on elongated body (424) distal region. With regard to claim 17 reciting the half-balloon structure, Swanson et

al discloses in Figure 84 each whole expandable structure (430) comprises the "half-balloon" structure, thus, deemed to have "half-balloon" structure. With regards to claim 17 now further defining the shape of the half-balloon structure that is asymmetric about the longitudinal axis of the elongate body distal region in a plane perpendicular to the longitudinal axis of the longitudinal body distal region, such asymmetric half-balloon shape is within ordinary skilled in the art particularly to procedures that requires asymmetric heating/ablating, resulting in asymmetric balloon as taught by Crowley (column 3 lines 46-53). Therefore, it would have been obvious to one skilled in the art to modify the Swanson et al's balloon structure (430) of Figure 84 such that it would be half-balloon asymmetric about the longitudinal axis in the plane perpendicularly to the longitudinal axis, as pointed out by Crowley suitable for applications asymmetric heating/abating.

Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson et al (U.S. Patent No. 6,076,012), modified above by Crowley (U.S. Patent No. 5,715,815) and further in view of Thompson et al (U.S. Patent No. 6,152,920). Swanson et al, presented above, discloses a tissue coagulation probe comprising elements as recited in these claims but does not suggest the hinge has a greater flexibility in the bending direction than the flexibility in the elongated body that are immediately proximal & distal thereto. Thompson et al discloses in Figures 14 & 15 a surgical probe (108) comprising a sheath (114) carried within an outer shaft (116), the sheath (114) defining a distal loop (110) supporting a plurality of electrodes (54) and a distal end connected to the outer shaft (116), the sheath (114) including a hinge portion (126) located proximal of the distal end, the hinge portion (126) is provided with a greater flexibility in the bending direction than the flexibility in the sheath (114) that are immediately proximal &

distal thereto. Therefore, it would have been obvious to one skilled in the art to modify the Swanson et al's probe to include a hinge, taught by Thompson et al for purposes of providing greater flexibility in the distal region of elongated body (184).

Claims 21-30, and 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson et al (U.S. Patent No. 6,076,012) and further in view of Thompson et al (U.S. Patent No. 6,152,920). Swanson et al, presented above, discloses a tissue coagulation probe comprising elements as recited in these claims, particularly to independent claims 21 and claim 25, the Swanson et al discloses the embodiment of Figure 25 comprising an elongated body (184) comprising a catheter carried within and extended outwardly from the outer member's (12) interior bore such that the distal region forms a loop including a cap or a hinge portion (186) defining the apex of the loop structure (170), the cap or hinge portion (186) is formed in the spline (172).

Regarding claim 22 reciting the control element, the embodiment of Figure 25 illustrates control elements (180, 192) associated with the distal end of elongated body (184) extending along the exterior of the elongated body (184).

Regarding claim 23, the embodiment of Figure 25 illustrates the loop structure (170) length is at least 2 times the loop height.

Regarding claim 26, the embodiment of figure 25 includes the coagulation body proximal to the hinge element and the electrodes (28) can be used to sense in heart tissue (column 7 lines 45-48). With regards to the limitations recited in the wherein statement in claim 26, particularly required the "sensing element" electrode on one side of the hinge portion and the "coagulation electrode" on the other side, it would have been clearly and obvious to one having ordinary skill

in the art at the time the invention was made to have the "sensing electrode" on a different side of the hinge portion from the "coagulation electrode", since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

With regards to claim 27, the Swanson et al discloses alternatively, the electrodes (28) can be space & sized for creating continously, long lesion pattern (418) as shown in Figure 64 and such pattern (418) can be achieved using elongated electrode element from a porous material as shown in Figure 82. The Examiner maintains that it would have been obvious to provide the inflatable structure from the embodiment of Figures 82-84 on the embodiment of Figure 25 to provide an alternative treatment device, such as during a procedure that would require additive heating effects during tissue contact.

Regarding claims 28 & 29, the embodiment of Figures 82-84 illustrates each whole expandable structure (430) comprises the "half-balloon" structure, thus, deemed to have "half-balloon" structure, and the structure (430) comprises porous material (column 35 lines 49-51).

Regarding claim 30 reciting the "heated structure", the Swanson et al embodiment of Figures 82-84 discloses fluid (438) can be introduced to expand the structure (424) interacting with electrodes (429) to generate heat, which is consistent applicant's specification on page 13 lines 1-22, thus, meets the cited "heated structure" limitation.

Regarding claims 21 & 45, however, the Swanson et al reference does not suggest the hinge has a greater flexibility in the bending direction than the flexibility in the elongated body that are immediately proximal & distal thereto. Thompson et al discloses in Figures 14 & 15 a surgical probe (108) comprising a sheath (114) carried within an outer shaft (116), the sheath (114) defining a distal loop (110) supporting a plurality of electrodes (54) and a distal end

connected to the outer shaft (116), the sheath (114) including a hinge portion (126) located proximal of the distal end, the hinge portion (126) is provided with a greater flexibility in the bending direction than the flexibility in the sheath (114) that are immediately proximal & distal thereto. Therefore, it would have been obvious to one skilled in the art to modify the Swanson et al's probe to include a hinge, taught by Thompson et al for purposes of providing greater flexibility in the distal region of elongated body (184).

## *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Camtu T. Nguyen whose telephone number is 571-272-4799. The examiner can normally be reached on (M-F) 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Camtu T. Nguyen/
Examiner, Art Unit 3772
/Patricia Bianco/
Supervisory Patent Examiner, Art Unit 3772